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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,531	09/05/2003	Jose Remacle	035642-0103	5573

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EXAMINER	
STEELE, AMBER D	
ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/655,531	**Applicant(s)** REMACLE ET AL.	
	Examiner Amber D. Steele	**Art Unit** 1639	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 December 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 26 December 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *see the attached "Advisory Action Continued"*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 1-9.
   Claim(s) withdrawn from consideration: 10-30.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

    _____.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). 12/03/03
13. ☐ Other: _____.

/Jon D. Epperson/
Primary Examiner, AU 1639

Advisory Action Continued

The amendment filed December 26, 2007 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because of the following:

a. The proposed amendment requires further consideration and/or search (i.e. the new limitation "wherein said 5 major subfamilies of amine neurotransmitter receptors are dopamine, histamine, serotonin, adrenergic, and cholinergic receptors" of independent claim 1, the new limitation "wherien the 16 subtypes for cholinergic are CHRM1, CHRM2, CHRM3, CHRM4, CHRM5, CHRNA2, CHRNA3, CHRNA4, CHRNA5, CHRNA7, CHRNB1, CHRNB2, CHRNB3, CHRNB4, CHRND, and CHRNE" of claim 3, and the new limitation "wherein the 14 subtypes of trace amines are TA1, TA2, TA3, TA4, TA6, TA7, TA8, TA9, TA10, TA11, TA12, TA13, TA14, and TA15" of claim 4).

b. The proposed amendment may necessitate the modification of outstanding rejection(s) to address the new limitation (i.e. the new limitation "wherein said 5 major subfamilies of amine neurotransmitter receptors are dopamine, histamine, serotonin, adrenergic, and cholinergic receptors" of independent claim 1, the new limitation "wherien the 16 subtypes for cholinergic are CHRM1, CHRM2, CHRM3, CHRM4, CHRM5, CHRNA2, CHRNA3, CHRNA4, CHRNA5, CHRNA7, CHRNB1, CHRNB2, CHRNB3, CHRNB4, CHRND, and CHRNE" of claim 3, and the new limitation "wherein the 14 subtypes of trace amines are TA1, TA2, TA3, TA4, TA6, TA7, TA8, TA9, TA10, TA11, TA12, TA13, TA14, and TA15" of claim 4).

c. The proposed amendment may necessitate the raising of new prior art rejections (i.e. the new limitation "wherein said 5 major subfamilies of amine neurotransmitter receptors are dopamine, histamine, serotonin, adrenergic, and cholinergic receptors" of independent claim 1, the new limitation "wherien the 16 subtypes for cholinergic are CHRM1, CHRM2, CHRM3, CHRM4, CHRM5, CHRNA2, CHRNA3, CHRNA4, CHRNA5, CHRNA7, CHRNB1, CHRNB2, CHRNB3, CHRNB4, CHRND, and CHRNE" of claim 3, and the new limitation "wherein the 14 subtypes of trace amines are TA1, TA2, TA3, TA4, TA6, TA7, TA8, TA9, TA10, TA11, TA12, TA13, TA14, and TA15" of claim 4).

d. The proposed amendment may necessitate the raising of new 112 issues (e.g. written description; 35 USC 112, second paragraph; i.e. the new limitation "wherein said 5 major subfamilies of amine neurotransmitter receptors are dopamine, histamine, serotonin, adrenergic, and cholinergic receptors" of independent claim 1, the new limitation "wherien the 16 subtypes for cholinergic are CHRM1, CHRM2, CHRM3, CHRM4, CHRM5, CHRNA2, CHRNA3, CHRNA4, CHRNA5, CHRNA7, CHRNB1, CHRNB2, CHRNB3, CHRNB4, CHRND, and CHRNE" of claim 3, and the new limitation "wherein the 14 subtypes of trace amines are TA1, TA2, TA3, TA4, TA6, TA7, TA8, TA9, TA10, TA11, TA12, TA13, TA14, and TA15" of claim 4).

e. There is no convincing evidence under 37 CFR 1.116(b) why the proposed amendment was not earlier presented.

f. Applicants arguments of the 35 USC 112, second paragraph rejections and the prior art of record are moot since the arguments are based on the proposed amendments that have not been entered.

g. See the Arguments and Response section below pertaining to the 35 USC 112, first paragraph (written description) rejection.

h. For all the reasons above, the amendment does not place the application in better condition for allowance and/or appeal.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 3, 2003 is being considered by the examiner. Please note: the previously initialed and considered citations (see Office action mailed on November 17, 2006) have been crossed out. It is noted that the submission (i.e. IDS and reference) received on December 3, 2003 did not include a copy of WO 02/095065 (please refer to MPEP § 609.05(a)). A copy of WO 02/095065 was received on May 16, 2007 and a supplemental IDS was not provided. As a professional courtesy, the originally filed IDS (December 3, 2003) which references WO 02/095065 is being considered. Applicants are respectfully directed to MPEP § 609 for future IDS submissions.

Arguments and Response

Applicants' arguments directed to the rejection under 35 USC 112, first paragraph (written description), for claims 1-9 were considered but are not persuasive for the following reasons.

Applicants contend that the examiner continues to reject claims 1-9 because claim 6 states that capture probes can be derived from the sense or antisense strand of the gene encoding the receptor. In addition, applicants contend that the nucleic acids employed in the microarrays used in the methods are defined not by end-functionality, but by structure (i.e. the sequences of dopamine, histamine, serotonin, adrenergic, and cholinergic receptors). Furthermore, applicants

contend that comparing the ratios of gene expression of particular neurotransmitter receptors elucidates activation pathways and the nucleic acids employed in the microarrays are not the quintessence of the claimed invention.

Applicants' arguments are not convincing since the presently claimed invention lacks adequate written description. In response to the arguments regarding antisense probes, the antisense probes are not the sole determination of the lack of adequate written description, but merely exacerbates the lack of adequate written description for a method of analyzing activation pathways utilizing a microarray comprising capture probes. Applicants have not disclosed a single probe (i.e. sense or antisense) that would be "sufficient for obtaining the information on one neurotransmitter subtype" or a single probe that analyzed "activation pathways controlled by neurotransmitters". In response to the arguments regarding that the probes are not defined by end-functionality but by structure, it is noted that a single probe is not currently disclosed in the specification. The present specification as originally filed only refers to accession numbers associated with various neurotransmitters (i.e. specific sequences are not provided). Applicants are also reminded of the fluid nature of accession numbers which may be continuously updated, changed, retired, etc. Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., method step of comparing ratios) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). An excerpt of the 35 USC 112, first paragraph (written description rejection) is provided below:

The Specification teaches the names and accession numbers for some amine neurotransmitter receptors (please refer to Tables 1-4). However, the specification does not teach a single specific probe (sense or antisense) for any of the amine neurotransmitter receptors. Furthermore, the specification does not teach which sequences would be able to define the various subtypes from the other including closely related subtypes of receptors. Moreover, the specification does not teach which sequences correlate to activation pathways of the neurotransmitters. Therefore, one skilled in the relevant art would not reasonably conclude that the Applicants had possession of the entire scope of the presently claimed invention. With the exception of probes consisting of full-length sequences corresponding to the accession numbers in Tables 2 and 4 as disclosed by the specification, the skilled artisan cannot envision the method of claim 1.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS
January 2, 2008

/Jon D. Epperson/
Primary Examiner, AU 1639